



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOFOSBUVIR/ VELPATASVIR/ VOXILAPREVIR	VOSEVI	44428		GPI-10 (1235990380)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C, genotype 1, 2, 3, 4, 5, or 6 **AND** meet the following criterion?

- The patient is 18 years of age or older

If yes, continue to #2.

If no, continue to #5.

2. Does the patient have an HCV RNA level within the past 6 months?

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet at least **ONE** of the following criteria?

- The patient is concurrently taking any of the following medications: amiodarone, rifampin, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifabutin, Priftin (rifapentine), HIV regimen containing atazanavir, lopinavir, Aptivus (tipranavir)/ritonavir, or efavirenz, rosuvastatin, Livalo/Zypitamag (pitavastatin), pravastatin (at doses above 40mg), cyclosporine, methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, sulfasalazine, topotecan, Sovaldi (sofosbuvir; as a single agent), Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), or Mavyret (pibrentasvir/glecaprevir)
- The patient has moderate or severe hepatic impairment (Child-Pugh B or C)
- The patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (e.g., physician attestation)

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #4.

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GUIDELINES FOR USE (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?

- Genotype 1-6, treatment experienced and previously failed a full course of therapy with DAA regimen that includes NS5A inhibitor [e.g., Harvoni (ledipasvir/sofosbuvir), Epclusa (elbasvir/grazoprevir), Technivie (ombitasvir/paritaprevir/ritonavir), Viekira Pak or Viekira XR (dasabuvir/ombitasvir/paritaprevir/ritonavir), Zepatier (elbasvir/grazoprevir), Daklinza (daclatasvir)/Sovaldi (sofosbuvir) combination]
- Genotype 1a or 3, treatment experienced and previously failed a full course of therapy with DAA regimen that includes sofosbuvir without NS5A inhibitor [e.g., Sovaldi (sofosbuvir)/ribavirin, Sovaldi (sofosbuvir)/peginterferon/ribavirin, Olysio (simeprevir)/Sovaldi (sofosbuvir) (or other HCV protease inhibitor in combination with Sovaldi (sofosbuvir)]

If yes, **approve for 12 weeks by HICL or GPI-10 for #1 per day.**

If no, continue to #5.

5. Is the requested regimen recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment?

If yes, **approve as indicated per guidance in AASLD/IDSA.**

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR (Vosevi)** requires the following rule(s) be met for approval:

- A. The requested regimen is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment
- B. You have chronic hepatitis C (type of liver inflammation)
- C. You are 18 years of age or older
- D. You have an HCV RNA level (amount of virus in your blood) within the past 6 months
(Denial text continued on next page)

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GUIDELINES FOR USE (CONTINUED)

E. You meet ONE of the following:

1. You have genotype 1, 2, 3, 4, 5, or 6 and previously failed a full course of therapy with a direct-acting antiviral (DAA) regimen that includes NS5A inhibitor [class of hepatitis C drug such as Harvoni (ledipasvir/sofosbuvir), Epclusa (elbasvir/grazoprevir), Technivie (ombitasvir/paritaprevir/ritonavir), Viekira Pak or Viekira XR (dasabuvir/ombitasvir/paritaprevir/ritonavir), Zepatier (elbasvir/grazoprevir), Daklinza (daclatasvir)/Sovaldi (sofosbuvir) combination]
2. You have genotype 1a or genotype 3 and previously failed a full course of therapy with DAA regimen that includes sofosbuvir without NS5A inhibitor [class of hepatitis C drug such as Sovaldi (sofosbuvir)/ribavirin, Sovaldi (sofosbuvir)/peginterferon/ribavirin, Olysio (simeprevir)/Sovaldi (sofosbuvir) (or other hepatitis c virus protease inhibitor in combination with Sovaldi)]

Vosevi will not be approved if you meet any of the following:

- A. You are using the requested agent concurrently (at the same time) with any of the following medications: amiodarone, rifampin, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifabutin, Priftin (rifapentine), HIV (human immunodeficiency virus) regimen containing atazanavir, lopinavir, Aptivus (tipranavir)/ritonavir, or efavirenz, rosuvastatin, Livalo or Zypitamag (pitavastatin), pravastatin (at doses above 40mg), cyclosporine, methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, sulfasalazine, topotecan, Sovaldi (sofosbuvir, as a single agent), Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), or Mavyret (pibrentasvir/glecaprevir)
- B. You have moderate or severe hepatic (liver) impairment (Child-Pugh B or C)
- C. You have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vosevi.

REFERENCES

- Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at <http://www.hcvguidelines.org/full-report-view> Accessed July 7, 2017.
- Vosevi [Prescribing Information]. Foster City, CA: Gilead Sciences; November 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/23

Created: 08/17

Client Approval: 08/23

P&T Approval: 07/23